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**OFFICE OF PETITIONS
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ON PETITION

In re Application of
Nancy Chang
Application No. 06/659,339
Filed: October 10, 1984
Attorney Docket No. CTR84-7

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This is a decision on the renewed petition under 37 CFR 1.182, filed May 28, 1996 to amend the above-identified abandoned application by insertion of a reference to the pre-filing date deposit of a recombinant phage clone, λ BH-10, harboring HTLV-III DNA.

The petition is **DENIED**.

BACKGROUND

The instant application was filed October 10, 1984, naming Nancy Chang as sole inventor.

On May 16, 1986, papers were filed seeking to amend the inventive entity to include Flossie Wong-Staal, and James Gallo, which was never treated by the examiner during the pendency of the application.

On December 15, 1986, an office action was mailed which set a three month period for response, and which *inter alia*, rejected all the elected claims under 35 USC 112 first paragraph, as lacking an adequate written description of the invention and for failing to provide an enabling disclosure, and also noted that "The invention appears to employ novel microorganisms, such as OmpA and pHR100, which were not deposited. It is not clear if the written description is sufficiently clear to avoid the need for a deposit, which must meet the criteria set forth in MPEP 608.01(p)(C)."

As no response was received within the period set and no extensions of time were requested, this application became abandoned March 16, 1987.

A Notice of Abandonment was mailed July 20, 1987.

During litigation not directly involving the instant inventors and assignee, reported as Chiron Corporation v. Abbott Laboratories, 902 F.Supp. 1103 (N.D. Cal. 1995), findings of law were made regarding the (in)sufficiency of the disclosure of the instant specification, under 35 USC 112, first paragraph, and findings of fact including that the specification as filed made no reference to any deposit of biological material.

On February 22, 1996, a petition was filed under 37 CFR 1.182 seeking to (1) insert a reference under 35 USC 120 to application No. 06/643,306, which was pending from August 20, 1984 through July 14, 1987, and (2) insert a reference to the pre-filing date deposit of a recombinant phage clone, ABH-10, harboring HTLV-III DNA. Petitioner relied upon, respectively, Sampson v. Commissioner of Patents, 195 USPQ 136 (D.D.C. 1976), and In Re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985) as authorities for the proposed amendments.

On March 29, 1996, a decision was mailed which granted the first requested item, and dismissed the second, noting that the two issues were independent, and separately decidable.

The instant petition, renewed only with respect to the second item, was filed May 28, 1996.

Petitioner continues to assert that (1) the requested insertion of a reference to the deposit is proper as the biological material is specifically identified in the specification as filed, and (2) the insertion of the reference is not new matter. As to the first issue, petitioner further submits that there is no requirement in the rules, examining procedures, or in Lundak, that a specification as filed must refer to a deposit of a biological material.

STATUTE AND REGULATIONS

35 USC 112, first paragraph requires that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 USC 114 provides in pertinent part:

When the invention relates to a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment.

35 USC 131 states

The Commissioner shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor.

35 USC 132 states:

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Commissioner shall notify the applicant thereof stating the reasons for such rejection or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. **No amendment shall introduce new matter into the disclosure of the invention.** (emphasis added)

35 USC 133 states:

Upon failure of the applicant to prosecute the application within six months after any action therein, of which notice has been given or mailed to the applicant, or within such shorter time, not less than thirty days, as fixed by the Commissioner in such action, the application shall be regarded as abandoned by the parties thereto, unless it be shown to the satisfaction of the Commissioner that such delay was unavoidable.

37 CFR 1.802(c) states:

The reference to a biological material in a specification disclosure or the actual deposit of such material by an applicant or patent owner does not create any presumption that such material is necessary to satisfy 35 U.S.C. 112 or that deposit in accordance with these regulations is or was required.

37 CFR 1.804(a) states:

Whenever a biological material is specifically identified in an application for patent as filed, an original deposit

thereof may be made at any time before filing the application for patent or, subject to 1.809, during pendency of the application for patent.

37 CFR 1.808 states that:

(a) A deposit must be made under conditions that assure that:

- (1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 1.14 and 35 U.S.C. 122, and
- (2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

37 CFR 1.809 provides in pertinent part:

(a) The examiner shall determine pursuant to 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under the appropriate provision of 35 U.S.C. 112, explaining why a deposit is needed and /or why a deposit actually made cannot be accepted.

(b) The applicant for patent or patent owner shall respond to a rejection under paragraph (a) of this section by --

- (1) In the case of an applicant for patent, making an acceptable original or replacement or supplemental deposit or assuring the Office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of 1.805, or

- (2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered nonresponsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.

OPINION

The proposed amendment, in this case, does not adequately comply with the applicable rules and statutes, to permit insertion.

Petitioner asserts that the referenced material of the deposit is identical to that disclosed in the specification, and includes a declaration by Dr. Flossie Wong-Staal (Staal) to that effect. As such, petitioner asserts, the deposit is in compliance with the deposit rules 37 CFR §§ 1.801-1.809 (specifically 37 CFR 1.804(a)), and MPEP § 2400, and therefore, the proposed insertion is proper. Petitioner's contentions are without merit, as the deposit has not been made in accordance with the deposit rules and patent statutes. As such, the mere assertion of identity between the material deposited by Staal, and that disclosed in the specification, is immaterial to the requested insertion of a reference to the material deposited by Staal.

Rather, the meaning of 37 CFR 1.804(a) is that a biological material may be acceptably deposited before filing an application if an adequate antecedent basis for the deposit subsequently exists in that application as *filed*. 54 FR 34864 (August 22, 1989). However, as set forth in the examiner's action mailed December 15, 1986, and as held in Chiron, this application, as *filed*, did not comply with 35 USC 112, and as such, did not provide adequate antecedent basis for referencing a deposit. Chiron held that this specification as *filed* did not specifically mention the clone sought to be inserted herein (at 1126), and further, failed to disclose the means for obtaining the necessary starting material to practice the invention (at 1129). It follows that the specification as *filed* did not provide adequate antecedent basis for the deposit, and, as such, cannot now be properly referenced to the deposit. Further, as noted in 54 FR 34869, "[I]t must be clear from the application as filed that the invention claimed and described in the specification "was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require no more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process)[.]", a situation clearly not present here. Petitioner's reliance on 37 CFR 1.802(c) is inapt, as the deposit rules do not address the substantive issue of whether a deposit is required under any particular set of facts. 54 FR 34864. Rather, the examiner addresses that substantive issue, as "reference to a biological material cannot be added to a specification without risking the prohibited introduction of new matter (35 U.S.C. 132)." 54 FR 34875-34876. Petitioner's further reliance on 37 CFR 1.809 is similarly misplaced, as the regulation speaks to procedures that will be used by the examiner to address deposit issues. 54 FR 34878. However, the examiner has no procedural authority with respect to

an abandoned application. Lorenz v. Finkl, 333 F.2d 885, 891, 142 USPQ 26, 30 (CCPA 1964).

As noted in the previous decision, this application was pending from October 10, 1984, through March 15, 1987. Petitioner appears to overlook the fact that, as noted in MPEP 2402:

"The rules are effective for all applications filed on or after January 1, 1990,...except that deposits made prior to the effective date which were acceptable under the then current practice will be acceptable in such applications and proceedings. Since most of the provisions of the rules reflect policy and practice existing prior to January 1, 1990, little change in practice or burden on applicants for patent... has occurred. Applicants and patent owners are encouraged to comply with these rules even if their applications and reexamination proceedings were filed prior to January 1, 1990. The current text of MPEP § 608.01(p)(C) is controlling practice for applications filed prior to January 1, 1990"

It should be noted that the practice for making an acceptable deposit prior to January 1, 1990, specified:

"When the invention depends on the use of a microorganism which is not so known and readily available, applicants must take additional steps to comply with the requirements of § 112. [The court in] In re Argoudelis, et al., 168 USPQ 99 (CCPA, 1970), accepted a procedure for meeting the requirements of 35 U.S.C. 112. Accordingly, the Patent and Trademark Office will accept the following as complying with the requirements of § 112 for adequate disclosure of the microorganism required to carry out the invention:

- (1) the applicant, no later than the effective U.S. filing date of the application, has made a deposit of the microorganism in a depository ... **under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 USC 122 and (b) that all restrictions on the availability to the public of the culture will be irrevocably removed upon the granting of the patent;**
- (2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification;

(3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.

A copy of the applicant's contract with the depository may be required by the examiner to be made of record as evidence of making the culture available under the conditions stated above." (emphasis added)¹

Since the instant specification as filed, and during pendency of the patent application, made no reference to a deposit, *inter alia*, and thus, the examiner was denied awareness of, and access to, the deposit, 35 USC 112 and 114 were not satisfied. Such is not an acceptable deposit procedure, then and now, and moreover, such failed to rise to the circumstances of Lundak. As such, petitioner's reliance upon Lundak is a *non-sequitur*.

Notwithstanding that this application was filed prior to January 1, 1990, petitioner improperly seeks to rely upon the current deposit rules. Assuming, *arguendo*, they are applicable to this application, petitioner has not shown, nor is it apparent, how the current deposit rules can be satisfied in this instance. E.g., 37 CFR 1.808, requires in pertinent part:

"(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the application making reference to the deposit to one determined by the Commissioner to be entitled thereto under § 1.14 and 35 U.S.C. 122," (emphasis added)

It follows that access to the deposit cannot "be available" (or have been available) to the Office *during pendency* of this application, as required by the examiner in the office action mailed December 15, 1986², the regulations, and statutes (35 USC

¹ Lundak, at 1219, 227 USPQ at 92. Lundak's application was pending from March 26, 1981, through June 10, 1986, which compares reasonably with that of the instant application (October 10, 1984 through March 15, 1987) for considering the then current practice. The practice set forth above is that of MPEP § 608.01(p)(C), now more fully codified in the deposit rules.

² While petitioner complains that he was not a party to the recent Chiron litigation, the court's holdings of law and

112 and 114), for **pending** patent applications, Lundak, at 1222, 227 USPQ at 95, as (1) the deposit was not referenced in the instant application during its pendency, much less in the specification as filed, and (2) the deposit was not made "under conditions which assure", **during pendency** of the instant application, availability to one determined by the Commissioner to be entitled to such, or, after grant of a patent, unrestricted public availability. Id. at 1219, 227 USPQ at 92; Feldman v. Aunstrup, 517 F.2d 1351, 1354, 186 USPQ 108, 112 (CCPA 1975).

As noted in 54 FR 34839, "The Office will treat a deposit not made according to these regulations, however, as if no deposit had been made."

Petitioner has not shown how the requirements of 35 USC §§ 112, 114 for PTO access to a sample of petitioner's material **during pendency of this application**, and of 35 USC § 112, for public access after grant, were met by petitioner's deposit procedures. Cf. Lundak at 1222, 227 USPQ at 95. The making of a deposit in 1984, and the 1996 attempt to reference that deposit *nunc pro tunc* in an application examined in 1986 and abandoned in 1987 is not seen to be in accordance with the deposit rules, or the patent statutes. As noted in Lorenz, at 889, 142 USPQ at 29:

"We think it is apparent however, that Congress did not intend that applicant should be able to 'prosecute' his application indefinitely before the Patent Office. An orderly administrative process demands an end to prosecution."

Rather, petitioner is using Chiron as an improper basis for the belated attempt to continue prosecution by responding to the examiner's action of ten years ago, and thereby finesse, *inter*

findings of fact regarding this application closely parallel sections of the examiner's action herein dated 10 years earlier. The record does not indicate why petitioner took no timely opportunity to be heard with regard to either situation. As to petitioner's further assertion that the Chiron litigation "may [not] preclude or estop Applicants from defending their applications", petitioner only had that opportunity with respect to this application while it was pending before the Office, and failed to then "defend" it. Cf. Sampson, where that applicant diligently and assiduously defended his rights, such that unusual delay or laches was not a bar to amending that abandoned application under 35 USC 120. Petitioner has failed to cite any authority for "defending" an abandoned application beyond the mere insertion of a § 120 statement, much less after a 10 year hiatus in activity.

alia, the doctrine of laches; the failure to comply with the deposit practice then in effect; the examiner's consideration of their belated response; and the abandoned status of this application. However, this application is abandoned by operation of law, and petitioner has made no attempt to revive this application under 35 USC 133, much less make a showing of unavoidable delay satisfactory to the Commissioner. It follows that petitioner will not be permitted, in the guise of a petition, to prosecute this application indefinitely before the Patent Office, and circumvent an orderly administrative process.

Petitioner's contentions with respect to the new matter issue are also without merit.

As explained in Dart Industries v. Banner, 636 F.2d 684, 688, 207 USPQ 273 at 276 (C.A.D.C. 1973):

"An addition to a patent specification constitutes new matter when it changes the invention disclosed or introduces a concept not previously present in that specification."
[citations omitted].

An amendment to the specification of a pending application must be considered by the examiner for new matter pursuant to 35 USC 132; however, the examination of an application pursuant to 35 USC 131 et seq. involves pending applications. Lorenz, Id.

Moreover, the fact that the Patent Office permits an amendment to an application without objection thereto as new matter during the examination process is given special deference by the courts. See, Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1573, 24 USPQ2d 1401, 1414 (Fed. Cir. 1992). The requested amendment of this abandoned application by petition would operate to evade the examination of such amendment for new matter pursuant to 35 USC 131 and 132³, as well as the requirement of the deposit regulations and 35 USC §§ 112, 114 that the material

³ The previous decision permitted petitioner to insert only the technical information required to obtain a benefit under 35 USC § 120, under the authority of Sampson. However, it is well settled that, since a § 120 statement is merely a mechanism for obtaining the benefit of the filing date of an earlier application, which mechanism does not change the invention disclosed in, or introduce a concept not previously disclosed into, the later application, there was no issues(s) of new matter. As such, no examination of this abandoned application, or the amendment, for new matter was required, or evaded. In re Lambrecht, 202 USPQ 620 (Comm'r Pat. 1976).

be (or have been) available to the examiner and Office for examination during pendency.

Petitioner challenges the previous decision where it stated that Lundak's specification as filed made reference to a deposit. Nevertheless, the specification as filed in Lundak specifically made reference to a deposit, i.e., the concept of deposit was present in the specification as filed. Id. at 1223, 227 USPQ at 95. Lundak erroneously believed, and the specification reflected his belief, that the deposit had been made with the ATCC prior to filing, when in fact the deposit was made about one week later. Note also, Lundak asserted that he deposited the material at his university, and elsewhere, prior to filing. In this light, the court ruled that the subsequent addition of merely the date of deposit and accession number did not constitute new matter.⁴ As such, and contrary to petitioner's contentions, Lundak does not authorize that reference to a deposit per se may be inserted for the first time into a pending application, much less into an abandoned application. Rather, Lundak merely held that when a specification as filed: otherwise satisfies 35 USC 112, and contains reference to a deposit of biological material; the insertion of an updated date of deposit and accession number to the pre-existing deposit statement in the specification of a pending application does not constitute new matter. Where, as here, the application is not pending, the specification does not satisfy 35 USC 112⁵, and does not, as filed, contain a reference to a deposit⁶, the conclusion is inescapable that Lundak is inapposite.

While petitioner asserts that Lundak held that the insertion of deposit data is not new matter as prohibited by 35 USC 132, a fair reading of the decision reveals this holding is actually limited to insertion of "[a]n accession number and deposit date" into the deposit statement. Id. at 1223, 227 USPQ at 96. As noted *supra*, the specific reference to the concept of deposit was present in the Lundak specification as filed. Therefore, the addition of "[a]n accession number and deposit date" was not a new concept prohibited by 35 USC 132. See also In re Fouche, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971).

Where petitioner argues that as the Staal deposit of λBH-10 complies with the governing deposit regulations, and thus, the

⁴ 3 D. Chisum, Patents § 7.03[5] (1997).

⁵ Chiron, Id. at 1126, 1127.

⁶ Chiron, Id. at 1108.

addition of a reference to the deposit of same is not new matter, such is a *non sequitur*. The deposit rules are subservient to the statutory prohibition of the insertion of new matter into a specification. 35 USC 132. Even assuming, *arguendo*, that the deposited material ABH-10 is that disclosed in the specification, the specification never made reference to a deposit of the material. Absent such, the proposed amendment does not amount to an acceptable mere change of wording, as it introduces a concept *i.e.*, deposit, not previously set forth. Fouche, Id.⁷ Rather, the proposed amendment is an incorporation by reference of the deposited material. Ex Parte Maizel, 27 USPQ2d 1662, 1669 (BPAI 1992). However, a specification that fails to comply with 35 USC 112, first paragraph, as filed, may not be thereafter augmented, as such would entail the addition of new matter within the meaning of 35 USC 132. In re Hay, 534 F.2d 917, 189 USPQ 790 (CCPA 1976). Specifically, a post-filing attempt at incorporation by reference is prohibited where such would entail the addition of new matter. Dart, Id.; In Re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973).

Even assuming, *arguendo*, that insertion of reference to a deposit is not an incorporation by reference, petitioner has failed to meet his burden of showing where the concept of deposit was set forth with reasonable precision in the specification as filed. Absent such a showing, the proposed introduction of the concept of deposit must be regarded, as a threshold determination, as the proposed, but prohibited, insertion of new matter. Fouche, Id.; Dart, Id.; Hawkins, Id.

Petitioner asserts that the instant request is akin to the § 120 statement authorized in the previous decision under Sampson, in that there is no need to examine a proposed § 120 statement for new matter. However, as noted in the previous decision, Dart makes it clear that insertion of a mere § 120 statement, cannot enlarge or alter the disclosure of an abandoned application, and cannot introduce a concept not previously set forth in that

⁷ The specification of Fouche, as filed, contained a specific, but incomplete, referencing statement to another application which therein set forth the necessary enabling disclosure of how to make Fouche's starting material. The court held that this was an adequate incorporation by reference such that a subsequent amendment to specify serial number and filing date did not introduce new matter into the specification. Id. Compare, Lundak's as-filed specification which contained a specific reference to a deposit, and the court's ruling that a subsequent amendment adding only the deposit number and deposit date did not introduce new matter into the specification.


disclosure. As such, there is no need to reexamine an abandoned application and a § 120 statement when inserting such into that abandoned specification under the authority of Sampson. In re Lambrech, 202 USPQ 620 (Comm'r Pat. 1976). Absent an equally clear and convincing authority for a threshold determination that insertion of a reference to a deposit, which reference is submitted after the filing, much less the abandonment, of an application, will not enlarge or alter the disclosure of that application, or will not introduce a concept not previously set forth in that application as filed, that proposed amendment, and abandoned application, must be examined for a determination of new matter *vel non*. However, petitioner has overlooked the fact that the all proceedings related to the examination of this application have been terminated since March 16, 1987, and that the examiner has lacked any procedural authority with respect to this application since that date. Lorenz, supra.

Conclusion

The previous decision has been reconsidered, but for the reasons given above, will not be changed. The request to amend the specification by insertion of a reference to a deposit of any biological material, including ABH-10, is denied.

This abandoned application is being returned to the Files Repository.

Telephone inquiries related to this decision should be directed to Special Projects Examiner Brian Hearn at (703) 305-1820.



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